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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/591,632	06/09/2000	Susan Lindquist	27373/34978A	2820

7590 04/09/2002

Marshall O'Toole Gerstein
Murray & Borun
6300 Sears Tower
233 South Wacker Drive
Chicago, IL 60606-6402

EXAMINER
BRANNOCK, MICHAEL T

ART UNIT	PAPER NUMBER
1646	13

DATE MAILED: 04/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/591,632	Lindquist et al.
Examiner	**Art Unit**
Michael Brannock, Ph.D.	1646

-- Th MAILING DATE f this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Jan 24, 2002

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1, 2, 4, 7, 19, 20, 22, 24-32, 46, 48, 55-58, 60, 61, 63, 65-67, 81, 97, 101-118 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims all claims are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Status of Application: Claims and Amendments

1. Applicant is notified that the amendments put forth in Paper 12, 1/24/02, have been entered in full. Applicant's timely response to the restriction requirement (Paper 11, 10/2/01) is acknowledged. Applicant correctly points out that claim 81 was not included in the restriction requirement. In view of the subsequent confusion over the prior restriction requirement, and in view of the new claims presented, and upon reconsideration of the previous restriction requirement, the examiner deems it necessary to issue a new written restriction requirement, see below.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 4, 7, 19, 20, 22, 24-32, 46, drawn to polynucleotides encoding a SCHAG amino acid sequence and a protein of interest, classified in class 536, subclass 23.5.

II. Claims 26-32 drawn to polypeptides having a SCHAG amino acid sequence and a protein of interest, classified in class 530, subclass 350

III. Claims 48 and 97, drawn to methods of modifying a living cell, classified in class 435, subclass 252.3

IV. Claims 55-58, 60, 61, 63, drawn to methods of making a reactive SCHAG amino acid sequence, classified in class 435, subclass 69.1.

V. Claims 65-67, 81, 101-110, 115-118 drawn to polypeptides having a reactive SCHAG amino acid sequence, classified in class 530, subclass 402.

VI. Claims 111-114, drawn to polynucleotides encoding polypeptides having a reactive SCHAG amino acid sequence, classified in class 536, subclass 23.5.

3. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I, II, V and VI are directed to products that are distinct both physically and functionally, and are not required one for the other, and are therefore patentably distinct. Further, the protein of Groups II and V can be prepared by processes which are materially different from recombinant DNA expression of Groups I and VI, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Groups I and VI can be used other than to make the protein of Group II, such in gene therapy or as a probe in nucleic acid hybridization assays. The polynucleotides of Group I and the polynucleotides of Group VI are patentably distinct because one is not required for the use of the

other. Similarly, the polypeptides of Group II and the polypeptides of Group V are patentably distinct because one is not required for the use of the other.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups III and IV are directed to methods that are distinct both physically and functionally, are directed toward different goals, and are not required for the use of the other. Group III requires modifying a cell to produce a stable and altered phenotypic state, which is not required by Group IV. Group IV requires methods of constructing a reactive SCHAG domain, which is not required of group III.

The polynucleotides of Groups I and IV are related to the methods of Groups III and IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides are patentably distinct from each of the methods of Groups III and IV because the polynucleotides can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups III and IV are materially and functionally distinct from each other.

The polypeptides of Groups II and V are distinct from the methods of Groups III and IV because one is not required for the use of the other. Therefore, because these inventions are distinct for the reasons given above and because a search and examination of all the groups in one patent application would result in an undue burden, since the searches for the groups are not co-extensive, the classification is different, and the subject matter is divergent, restriction for examination purposes as indicated is proper.

4. The instant claims are generic to a practically limitless plurality of disclosed patentably distinct species comprising a multitude of polynucleotides or polypeptides, each polynucleotide and protein being a structurally and functionally distinct molecule, the use of one not being required for the use of any other. Further, a search of one could not be relied upon to provide art that is anticipatory of any other, and to search more than one polynucleotide or polypeptide in a single application would be burdensome.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of polynucleotide or polypeptide. If a polynucleotide group is elected, then Applicant is required to elect a single defined polynucleotide sequence or a polynucleotide that encodes a single defined polypeptide sequence. If a polypeptide group is elected, then Applicant is required to elect a single polypeptide sequence.

In addition, the claims of Group V are generic to plurality of disclosed patentably distinct species of substituent, e.g. an enzyme, a metal atom, a carbohydrate etc., see claim 109. a search

of one substituent could not be relied upon to provide art that is anticipatory of another, and to search all would be burdensome. If Applicant elects for prosecution Group V, then Applicant must also elect a species of substituent.

5. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Thursdays from 8:00 a.m. to 5:30 p.m. The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

April 4, 2002

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600